UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	36-01	9/5/01

RULES OF PRACTICE

1. Why is FSIS issuing this Notice?

FSIS is issuing this notice to ensure that all inspection program personnel are knowledgeable about the enforcement actions that the Agency may take (generally) in inspected establishments, the circumstances under which the various types of enforcement actions are appropriate and can be taken, and the procedures that the Agency will follow in doing so. The rules of practice provide a key link between inspection and enforcement activities.

2. What are the different types of enforcement actions that FSIS can take?

9 CFR 500.1 defines the three types of enforcement actions; they are:

--a "regulatory control action," that is, the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product;

--a "withholding action," that is, the refusal to allow the marks of inspection to be applied to products; a withholding action may affect all product in the establishment or product produced by a particular process; and

--a "suspension," that is, an interruption in the assignment of program employees to all or part of an establishment.

Withholding actions and suspensions have some similarities and in some past instances the Agency's use of these terms has blurred the distinctions between them as they are now defined in the rules of practice (such as when Agency documents discuss the "withholding of inspection"). To help clarify, it is useful to think about withholding as affecting whether the

marks

of inspection may be applied, while suspension affects whether inspection verification activities will be performed. Future Agency documents will use the terms as defined in the rules of practice.

Both withholding and suspension are different from a withdrawal of a Federal grant of inspection or a refusal to grant inspection. Withdrawal actions are initiated by the FSIS Administrator according to the Department of Agriculture's Uniform Rules of Practice, a different set of procedures, found at 7 CFR Subtitle A, part 1, subpart H. Historically, withdrawals have occurred infrequently. The Administrator may also refuse to grant Federal inspection.

3. What circumstances call for a regulatory control action?

9 CFR 500.2 lists the reasons for which FSIS may decide to take a regulatory control action. They are:

--insanitary conditions or practices;

--product adulteration or misbranding;

--conditions that preclude FSIS from determining that product is not adulterated or misbranded;

--inhumane handling or slaughtering of livestock.

Inspection program personnel will readily recognize that these are general reasons that could be discovered by a wide variety of inspection procedures. Regulatory control actions are limited focus actions that are to be used to address specific problems that inspection program personnel come upon in the course of their activities. When making a decision about whether a regulatory control action is appropriate, here are some factors to consider:

--A regulatory control action permits inspection program personnel to act quickly to secure correction of what may be a readily remediable situation.

Example: Direct product contamination with a contaminant that does not result in a food safety hazard. Also a regulatory control action could be applied to product that is economically adulterated.

--A regulatory control action may be followed by further determinations based on review of records or other facts. **Example**: A plant failed to monitor at their critical limit. The production process is not complete, therefore, no pre-shipment review has been conducted. It is the end of the shift for the inspection program personnel who is on a patrol assignment that includes this establishment. Inspection program personnel recognizes

that the establishment could realistically complete the process and the pre-shipment review prior to his/her return the following day. In other words, inspection program personnel is concerned that the product will be shipped prior to his/her return to the establishment the following day so he/she would retain the product until the establishment provides evidence that the critical limit was met or that the product produced is safe.

--A regulatory control action is usually the least burdensome enforcement action that the Agency can take; however, the burden of a regulatory control action increases with the amount of product affected or with the importance to operations of the rejected equipment or facility.

4. What procedures are to be used when inspection program personnel take a regulatory control action?

After determining that a regulatory control action needs to be taken, inspection program personnel will notify the establishment orally or in writing of the action and the basis for it. The written notification will be a Noncompliance Record (NR). Frequently, regulatory control actions can be resolved quickly, with the establishment taking an action like properly disposing of contaminated product or cleaning a specific piece of equipment and modifying its procedures to prevent recurrence of the problem. Once the situation has been corrected, inspection program personnel will conclude the regulatory control action.

An establishment may appeal a regulatory control action by following the procedures described in 9 CFR 306.5 and 381.35; these simple procedures direct establishments that want to appeal to bring the appeal to the next level of supervision, as has been the longstanding practice in the Agency.

5. What circumstances call for a withholding action?

Withholding actions are more significant than regulatory control actions and are used when the noncompliances raise questions about the condition of the affected product. Withholding the marks of inspection may be appropriate when there are multiple and recurring instances in which HACCP requirements, such as performing a pre-shipment review, are not met, and these recurrences are not interspersed with periods of compliance. FSIS believes that taking a longer term general enforcement action, like withholding the marks of inspection, should be based on multiple NRs, without demonstration by the establishment that it can control the process, i.e., intervening periods of successful control. As a result of these problems, inspection program personnel are unable to find that the products produced are not adulterated. Withholding the marks of inspection may affect all the products produced under a single process.

Example: In performing a verification procedure, an inspector determines that the new supply of pre-mixed spices, which is used in one cooked sausage product, does not meet regulatory requirements. The Agency decides to withhold the marks of inspection from all products produced using the spice mix.

In determining whether a withholding action is the appropriate enforcement tool, here are two factors to consider:

--A withholding action should be reserved for noncompliances that are more serious than those addressed by a regulatory control action;

--Withholding the marks of inspection should be applicable to an identifiable quantity and type of product.

Notification to an establishment about an enforcement action and the reason for it is **always** necessary. Taking a withholding action may require that written notification and an opportunity to achieve compliance can occur **before** the action is put into effect.

Note: The need to deny the use of the marks of inspection may occur after some product in the identifiable quantity of affected product has been shipped. Therefore, because the product inappropriately bears the mark of inspection, the product that has been shipped may need to be recalled or seized.

6. When is prior notification necessary before taking a withholding action? When is it optional? What is FSIS policy in this area?

The rules of practice specify when **prior** notification is necessary, and when it is optional. 9 CFR 500.4 lists the circumstances when advance notification and the opportunity to comply are necessary.

They are:

--the HACCP system is inadequate under 417.6;

--the Sanitation Standard Operating Procedures (Sanitation SOPs) have not been properly implemented or maintained under 416.13 through 416.16;

--the establishment has not maintained sanitary conditions;

--the establishment did not collect, analyze, or record results of samples for *E. coli* Biotype I, as per 310.25(a) or 381.94(a); or

--the establishment did not meet the *Salmonella* performance standard requirements under 310.25(b) or 381.94(b).

The purpose of prior notification with an opportunity to comply is to provide the establishment with due process protections. Inspection program personnel can see that the list above includes the kind of situations that do not occur suddenly. They arise over a period of time and have usually been the subject of NRs and discussions with the establishment. In the case of *Salmonella* performance standards, there is a lengthy time period before the failure occurs and also an elaborate notification and opportunity to comply built into current procedures. In the case of the first three items, the determinations require that the Agency compile extensive information and analyze it with care and good judgment. This makes it reasonable to provide the establishment with this information in advance. The establishment will have an opportunity to point out Agency factual errors, identify scientific or technical disagreements, and articulate differing interpretations of regulatory requirements. All this information is useful to FSIS in determining how to proceed.

9 CFR 500.3 lists the circumstances when **prior** notification may not be necessary, even though written notification must be accomplished promptly. They are:

--the establishment has produced and shipped adulterated product that the Agency has determined to present an imminent threat to public health;

--the establishment does not have a HACCP plan as specified under 417.2;

--the establishment does not have Sanitation SOPs as specified in 416.11-416.12;

--sanitary conditions are such that products are or would be adulterated;

--the establishment violated the terms of a regulatory control action;

--an establishment representative assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

--the establishment did not destroy condemned meat or poultry carcasses, or parts or products as specified in part 314 or 381, subpart L, within three days of notification.

Inspection program personnel will recognize that these are situations in which prompt action may be necessary to protect the public health or the safety of FSIS personnel. When this is the case, **but only in such cases**, a withholding action may be taken without prior notification. Inspection program personnel taking withholding actions without prior notification **must** be able to document the imminent threat to public health or to the

safety of

inspection program personnel that made prior notification infeasible. Multiple instances of economic adulteration do not justify taking a withholding action without prior notification to the establishment and the opportunity to achieve compliance.

As with other enforcement actions, establishments may appeal a withholding action by following the procedures in 306.5 or 381.35.

As a matter of policy and discussed above, FSIS inspection program personnel will provide prior written notification to the establishment whenever it is feasible. The only circumstances that justify later notification are an imminent threat to public health or to the safety of FSIS personnel. In the case of the latter, a withholding action may be a necessary but not sufficient enforcement response.

7. What circumstances call for a suspension?

The situations in which a suspension of FSIS inspection activities is appropriate are almost the same as those in which a withholding action could be taken. However, the preamble to the final rules of practice advises that a suspension of inspection is expected to have a greater impact on an establishment than a withholding action, and that a District Manager (DM) or higher level official makes the decision to suspend. Suspension actions are appropriate when establishments have been unable to implement corrective and preventive actions in response to withholding actions.

Suspension actions are also categorized into: (a) those that require prior notification to the establishment and an opportunity to comply; and (b) those that do not require **prior** notification.

Prior notification must be provided before taking a suspension for any of the following reasons:

--the HACCP system is inadequate under 417.6;

--the Sanitation SOPs have not been implemented or maintained under 416.13 through 416.16;

--the establishment has not maintained sanitary conditions;

--the establishment did not collect, analyze, or record results of samples for *E. coli* Biotype I, as per 310.25(a) or 381.94(a); or

--the establishment did not meet the *Salmonella* performance standard requirements under 310.25(b) or 381.94(b).

Again, these are circumstances that do not arise in a short time but have likely been the reason for multiple regulatory control actions or withholding actions. Prior notification provides the establishment with due process protections and enables the Agency to refine its thinking on how to proceed.

As with withholding actions, there are certain circumstances in which prior notification, although not required in the regulation, will be carried out by inspection program personnel whenever it is feasible. The situations are listed below; notice that the last reason is not on the similar list for withholding actions.

--the establishment has produced and shipped adulterated product that presents an imminent threat to public health;

--the establishment does not have a HACCP plan as specified in 417.2;

--the establishment does not have Sanitation SOPs as specified in 416.11 through 416.12;

--sanitary conditions are such that products are or would be adulterated;

--the establishment violated the terms of a regulatory control action;

--an establishment representative assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

--the establishment is handling or slaughtering animals inhumanely (9 CFR 500.3(b)).

Again, these are situations in which the need for prompt action may make prior notification infeasible. In cases in which there is an imminent threat to public health, threats, intimidation or interference with FSIS employees, or the inhumane handling or slaughter of animals, FSIS may need to take a suspension action without prior notification. The DM or a higher level official will make this determination.

As with other enforcement actions, the establishment may appeal a suspension under 306.5 or 381.35.

8. What is an abeyance, and when is it used?

9 CFR 500.5(e) is a provision for holding a suspension in abeyance. This is an important provision, and one that inspection program personnel need to understand. This provision permits FSIS to hold a **suspension** in

abeyance; the provision does not apply to any other enforcement action. An abeyance is a moratorium on the effect of a suspension. Once a suspension is imposed, the DM may put it into abeyance if the establishment undertakes corrective and preventive actions that the DM finds will ensure that the conditions that were the basis for the suspension will be eliminated, and recurrence of those conditions will be prevented. To provide the establishment with an opportunity to execute the plan, the DM will put the suspension into abeyance. The DM should not hold a suspension in abeyance for more than 90 days without a specific operational reason, such as intermittent production by the establishment under the suspended process.

9. What documents does FSIS use to notify establishments of enforcement actions?

To reiterate, it is FSIS policy that establishments be provided notification of any enforcement action taken by the Agency and the basis for it.

For regulatory control actions, inspection program personnel will notify the establishment orally at the time of the action and in writing, with a properly completed NR as soon as possible, usually during the same shift. The NR provides all the information that is necessary for written notification to establishments, including identification of the specific noncompliance. It invites the establishment to respond, and it provides information about the establishment's appeal rights.

For the withholding or suspension actions in which the establishment is not given prior notification, inspection program personnel should inform the establishment orally and in writing as soon as possible. 9 CFR 500.5(a) lists the information that must be included in the written notification. The notification must state:

--the type of action (withholding the marks of inspection or suspension of inspection verification activities) and its effective date;

--the reasons for the action;

--the products or processes affected by the action;

--a provision for the establishment to present corrective action and further planned preventive actions to address the noncompliance; and

--information to the establishment about its appeal rights under 306.5 and 381.35.

When prior notification and the opportunity to comply is required under 500.4 or as a matter of FSIS policy, the following information must be included:

--the type of action that FSIS may take;

--the reason for the pending action;

--the products or processes affected by the pending action;

--information to the establishment that it may contest the basis for the pending action or explain how compliance has been or will be achieved; and

--information to the establishment that it will have three business days to respond to this written notification, unless the DM decides to extend this time period.

These are Notices of Intended Enforcement (NOIEs); their issuance and management is carried out at the District Office level. FSIS Notice 5-01 describes the responsibilities of DMs in assessing establishment responses to these NOIEs.

10. What mechanisms does FSIS use to encourage compliance and prevent the need for enforcement actions?

Implementation of HACCP was not designed to proliferate situations that demand that FSIS take enforcement actions. Since the familiarization meetings before HACCP implementation, FSIS has expected that its personnel will communicate effectively with establishments and encourage them to use their HACCP and Sanitation SOP systems to prevent and correct problems before FSIS enforcement action is necessary.

FSIS still expects that in-plant personnel and the establishment will be having **weekly meetings** to discuss how things are going in the establishment. One subject of discussion could be **trends** in establishments performance, as revealed by trend indicators or other information such as early warnings on *Salmonella* set failures. These meetings might include review and analysis of the establishment's generic *E. coli* results or its experience in dealing with *Listeria*.

The Technical Service Center's (TSC) new correlation initiative will facilitate communication and understanding among inspection program personnel across districts, and between inspection program personnel and regulated establishments. This activity is designed to reduce variability in how inspection program personnel evaluate establishment compliance with regulatory requirements. **Example**: FSIS believes that inspection program personnel in some further processing establishments may have different ideas about the appropriate frequency of monitoring procedures than do the

inspection program personnel in some slaughter establishments. However, the scientific and technical guidance in such documents as the Food Code, does not make a distinction. FSIS would like all personnel verifying monitoring procedures in HACCP systems to have a similar scientific basis on which to make their determinations.

Another communication protocol that the Agency is now using to preclude the need for significant enforcement actions is the 30-day reassessment letter. This is commonly used in conjunction with an In-Depth Verification (IDV) review. When such a review turns up significant findings, especially concerning technical and scientific aspects of an establishment's HACCP system, those findings are presented and the establishment is provided with 30 days to reassess its HACCP plan before a decision on whether an NOIE should be issued is made. The Agency is now considering other situations in which a 30-day reassessment letter might be appropriate.

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